UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456
THIS DOCUMENT RELATES TO:	)	Civil Action No. 01-12257-PBS
U. S. ex rel. Ven-a-Care of the Florida Keys, Inc. v. Zachary T. Bentley, and T. Mark Jones v. Abbott Laboratories, Inc., NO. 07-CV-11618-PBS	)	Judge Patti B. Saris Magistrate Judge Marianne B. Bowler Leave to File Granted on June 10, 2008

PLAINTIFF VEN-A-CARE OF THE FLORIDA KEYS, INC.'S SUR-REPLY IN OPPOSITION TO ABBOTT LABORATORIES, INC.'S REQUEST FOR CERTIFICATION OF INTERLOCUTORY APPEAL UNDER 28 U.S.C. § 1292(b) AND STAY OF DISCOVERY PENDING APPEAL

Abbott's petition for interlocutory review should be denied. Abbott has not met, and cannot come close to meeting, the exacting requirements for certifying an interlocutory appeal under 28 U.S.C. § 1292(b). Specifically:

(1) There is no substantial ground for difference of opinion as to the correctness of this Court's March 14, 2008 order denying Abbott's motion to dismiss. The Court's ruling that the "first-to-file" bar did not apply to Plaintiff's Erythromycin complaint was entirely consistent with, and supported by, controlling case law, including well-established authority in this Court and within the First Circuit applying the "same material elements" test for determining when, if at all, a prior-filed action preempts a later action. Abbott agrees that the "same material elements" test is well-established, and has not cited a single opinion that conflicts with this Court's decision. Further, in this case the "material elements" of fraud necessarily include *particularized facts* with respect to the actual prices of Erythromycin NDCs. Because these "material elements" are indisputably absent from the earlier filed complaint, Plaintiff's Erythromycin complaint cannot possibly share the "same

material elements" with the intervened HPD case, and therefore the first-to-file rule does not bar the Erythromycin complaint.

(2) An immediate appeal of this Court's ruling would only make the litigation more protracted and expensive, and would not materially advance the ultimate termination of the litigation.

(3) Abbott has failed to raise a controlling question of law. The First Circuit defines controlling questions of law as *difficult and pivotal questions of law not settled by controlling authority*. As detailed below, the Court's ruling is consistent with and supported by clear, controlling authority and did not turn on difficult or pivotal questions of law not settled by controlling authority. Moreover, interlocutory appeals are granted only in *exceptional circumstances*. There are no such exceptional circumstances here.

Because it is wholly without merit, this Court should deny Abbott's request for interlocutory appeal.

I. THERE IS NO SUBSTANTIAL GROUND FOR DIFFERENCE OF OPINION AS TO THE CORRECTNESS OF THE COURT'S OPINION.

Abbott has not shown, and cannot show, that there is a substantial basis for difference of opinion with respect to the correctness of the Court's ruling. As this Court correctly determined in denying Abbott's motion to dismiss, Plaintiff's Erythromycin complaint is not barred by §3730(b)(5) because the earlier federal case "does not make any allegations relating to Erythromycin." This conclusion is entirely consistent with the clear language and established purpose of §3730(b)(5), as well as settled law holding that later-filed *qui tam* complaints are barred under §3730(b)(5) *only* when the later-filed complaint (1) alleges "all the same material elements" of fraud as the first-filed action and (2) gives rise to the same damages as the earlier action. *See,*

e.g., United States ex rel. Capella v. United Techs. Corp., 1999 U.S. Dist. LEXIS 10520, *9 (D. Conn. 1999).

Abbott's misguided attempt to conjure a difference of opinion by asserting that the Court's order imposes an "identical facts" requirement is entirely baseless and should be rejected out of hand. As Abbott acknowledges, there is near-unanimous agreement that the first-to-file bar applies only when the later-filed complaint contains the "same material elements" of the fraud. And as this Court has made clear on numerous occasions, the "material elements" of fraud in AWP cases – which must be plead with particularity under Fed. R. Civ. P. 9(b) – include the "factual allegations regarding a spread[.]" *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 2004 WL 2387125, at *2 (D. Mass. Oct. 26, 2004). Because the first-filed complaint did not contain particularized facts such as the transactional pricing data for Erythromycin NDCs, it obviously cannot satisfy the requirements of Rule 9(b) with respect to Plaintiff's Erythromycin claims.

The Court's commonsense ruling – that no first-to-file argument can be leveled against Plaintiff on the basis of claims not actually previously alleged – is clearly consistent with the uniformly-applied "same material elements" standard. Thus, there is no ground – substantial or otherwise – for a difference of opinion.[1]

A. This Court's Decision is Entirely Consistent With, and Properly Applies, the "Same Material Elements" Test to Plaintiff's Erythromycin Claims

As Abbott appears to concede, there is near-universal agreement that a *qui tam* complaint is "related" to an earlier *qui tam* action – and thus barred under §3730(b)(5) – *only* if it (1) alleges

[1] The cases Abbott cites in support of its request for certification are not to the contrary, but are simply inapposite, as Plaintiff has demonstrated in its prior briefs in opposition to Abbott's motion to dismiss and in opposition to Abbott's request for interlocutory certification.

the same material elements of fraud and (2) gives rise to the same damages. *See, e.g., United States of America ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 2008 WL 244304 at *8 (D. Mass. Jan. 25, 2008) (observing that "[a]lthough the First Circuit has not yet spoken to this issue, the majority of courts interpret §3730(b)(5) to bar a later allegation which "states all the essential facts of a previously-filed claim") (quoting *United States ex rel. St. John LaCorte v. Smithkline Beecham Clinical Lab., Inc.*, 149 F.3d 227, 232 (3d Cir. 1988)*; Grynberg v. Koch Gateway Pipeline Co.*, 390 F.3d 1276, 1279-80 (10th Cir. 2004) ("every other circuit to have addressed this issue...[has adopted] an 'essential claim' or 'same material elements' standard"); *Capella*, 1999 U.S. Dist. LEXIS 10520, at *9*; United States ex rel. Erikson v. American Institute of Biological Sciences*, 716 F. Supp. 908, 918 (E.D. Va. 1989) (later-filed action not barred under §3730(b)(5) unless "it gives rise to a separate recovery of actual damages by the government.").

It is also uniformly acknowledged that "[t]he strictures of Rule 9(b) limit the preclusive effect of the first-filed complaint to *claims that can be pleaded with particularity*[.]" *United States ex rel. Ortega v. Columbia Healthcare, Inc.*, 240 F. Supp.2d 8, 13 (D.D.C. 2003) (emphasis added). In other words, the facts which are "material" or "essential" for purposes of §3730(b)(5) are at a minimum those required to be included in a complaint under Rule 9(b) of the Federal Rules of Civil Procedure.

As the First Circuit has held, "[e]vidence of an actual false claim is the *sine qua non* of a False Claims Act violation," and therefore, "the details of the actual presentation of false or fraudulent claims to the government can and must be pled with particularity in order to meet the requirements of Rule 9(b)." *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 225 (1st Cir. 2004); *see also Duxbury*, 2008 WL 244304 *12 ("[I]it is not enough to allege

details of the scheme if there are not also particularized allegations regarding the false claims that were actually submitted to the federal government"). Moreover, this Court, as noted above, has repeatedly held that fraudulent pricing claims will not satisfy Rule 9(b) unless the complaint includes particularized allegations regarding the spread for each particular drug. *See, e.g., In re Pharmaceutical Industry Average Wholesale Price Litigation*, 2004 WL 2387125 at *2; *In re Pharm. Indus. Average Wholesale Price Litig.*, April 2, 2007 Memorandum and Order, Docket #3979 at p. 36, n.8 (finding that plaintiffs satisfied Rule 9(b) by relying in part on actual market prices provided by VAC).

Courts routinely rely on the requirement of particularity – the "who, what, when, where and how" of the alleged fraud – as protection against broad allegations in a first suit thwarting later claims. For example, in *Duxbury*, 2008 WL 244304 at *12, this Court held that a "bare bones allegation" that did not provide the "essential facts" regarding a drug manufacturer's scheme to promote off-label uses for a drug could not "act as a placeholder" precluding later FCA claims regarding that same scheme. Similarly, in *Walburn v. Lockheed Martin Corp.*, 431 F.3d 966, 971 (6th Cir. 2005), the Sixth Circuit analyzed two *qui tam* complaints filed against the same defendant for arguably the same fraudulent activity. The court held that "broad and conclusory allegations" in the first complaint could not preempt later claims where the earlier allegations were "legally insufficient under Rule 9(b) because they fail to provide 'the time, place and content' of any of the allegedly fraudulent claims submitted to the government." The *Walburn* court specifically held that "[o]nly a complaint that complies with Rule 9(b) can have preemptive effect under § 3730(b)(5). Likewise, in *Capella*, 1999 WL 464536, at *10-11, the court rejected a first-to-file challenge where two different relators made "similar factual allegations" concerning false claims presented to the

government. The court reasoned that because "the falsity of a claim or record constitutes an essential element of a FCA violation," each relator would be required to "prove distinct sets of facts to show that such claims were false or fraudulent." *Id.* at *10.

By definition, since the first-filed complaint did not even make any "allegations relating to Erythromycin," as this Court correctly ruled, the later-filed Erythromycin complaint cannot allege the "same material elements" of fraud nor give rise to the same damages as the intervened HPD case. Indeed, it is clear from even a cursory comparison of the facts alleged by Plaintiff in this case with those raised in the intervened HPD case that Plaintiff's Erythromycin claims are not barred by §3730(e)(4) because the material elements of fraud in the two complaints are different and Plaintiff seeks a separate recovery.

Two separate claims for FCA violations cannot share the same material elements if they are based on entirely different false claims – in this case, different drugs, sold by different people, to different market segments, with different pricing data and different spreads, separate FCA violations, and separate damages. Here, it is beyond dispute that Plaintiff's allegations in the intervened HPD case – which alleged fraud *only* with respect to infusion drugs sold in the outpatient market of specialty providers – did not include the actual prices of specific Erythromycin drugs. Because this essential pricing information, which VAC provided to the government, and which was otherwise unavailable to the government, was clearly absent from the intervened HPD case, Plaintiff's Erythromycin complaint cannot possibly share "all the essential facts" or all the same "material elements" of the fraud alleged in the earlier complaint.[2]

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[2] As Plaintiff has demonstrated, Abbott's suggestion that the later-filed complaint is barred because the government purportedly had the ability to discover the Erythromycin fraud by investigating the allegations in a prior complaint is totally contrary to the evidentiary record that has

Furthermore, it is obvious that the intervened HPD case will not permit the federal government to recover damages caused by the pricing fraud in the PPD Division involving the Erythromycin products. Where, as here, the later-filed complaint would enable the government to secure "two separate and distinct recoveries for actual damages incurred as the result of the defendants' conduct," courts have declined to apply §3730(b)(5)'s bar. *See Capella*, 1999 WL 464536 at *10-11; *Erickson*, 716 F. Supp.2d at 918-19. This principle is consistent with the purpose of the 1986 amendments to the FCA, which added §3730(b)(5). Suits alleging different material facts are to be encouraged, because they have the potential of increasing returns to the United States Treasury. In addition, facts that can result in increased recovery to the federal fisc clearly are "material" or "essential" to that outcome.

Because Abbott has not come close to demonstrating that there is any "substantial ground for difference of opinion" about this Court's order, its request for certification should be denied.[3]

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developed in all of the AWP cases in the MDL. Abbott's contention is also completely contrary to the language of §3730(b)(5) and the purpose of the 1986 amendments to the FCA. The first-to-file statute is limited to the "facts underlying the pending action," and therefore cannot include other facts not disclosed in the complaint. Further, when it eliminated the "government knowledge" bar in 1986, Congress emphatically rejected the proposition that, simply because the government is in possession of information which, if followed up on, could lead to the discovery of other frauds, an individual should be precluded from filing a *qui tam* action based upon such fraud.

[3] Abbott continues to press its misleading and incorrect argument that the later-filed complaint should be barred because certain Erythromycin NDCs appeared in the earlier case. The Erythromycin NDCs were not added to the intervened HPD case until December 2002, well after the 2001 Erythromycin complaint was filed. Because the first-to-file analysis focuses on when particular claims were brought in each of the cases at issue, not merely which case was initiated first, Abbott's contention is without merit. *See, e.g.*, *Ortega*, 240 F. Supp. 2d at 14 & n.6.

II. AN IMMEDIATE APPEAL OF THE ORDER WILL DELAY THE ULTIMATE TERMINATION OF THIS LITIGATION, NOT ADVANCE IT.

Abbott also fails to meet the requirement that an immediate appeal would materially advance the ultimate termination of the litigation. Interlocutory review in this case would have exactly the opposite effect, as certification of the Court's order would delay discovery and almost certainly delay the termination of this litigation**.**

This case will require relatively little additional discovery on account of the extensive litigation against Abbott in the intervened HPD case, Abbott's extensive discovery against the federal government and plaintiff VAC, and the assumption that prior discovery can be used in this case. The federal government has already represented that they have gathered the Medicaid utilization data for these drugs and VAC has already produced virtually all of its documents. There should be considerable judicial efficiency in putting the Erythromycin and intervened HPD case on some coordinated track.

III. ABBOTT HAS FAILED TO RAISE A CONTROLLING QUESTION OF LAW.

The First Circuit has repeatedly stressed that interlocutory appeal under §1292(b) "should be used sparingly and only in exceptional circumstances, and where the proposed intermediate appeal presents one or more difficult and pivotal questions of law not settled by controlling authority." *In re San Juan Dupont Plaza Hotel Litigation*, 859 F.2d 1007, 1010 n.1 (1st Cir. 1988) (quoting *McGillicuddy v. Clements*, 746 F.2d 76 n.1 (1st Cir. 1994)). Thus, the First Circuit defines a controlling question of law as a "'difficult and pivotal question[] of law not settled by controlling authority." *Id.*

Abbott falls far short of showing any "exceptional circumstances" in this case, and as the foregoing discussion makes clear, the Court's order is consistent with settled and controlling law

on the first-to-file issue. Because Abbott fails to satisfy any of the requirements for interlocutory review, its request for certification should be denied.

CONCLUSION

For all of the foregoing reasons, Plaintiff respectfully requests that the Court deny Abbott's request for certification of an interlocutory appeal and stay of discovery.

Dated: June 16, 2008

Respectfully submitted,
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CERTIFICATE OF SERVICE

I do hereby certify that a true and correct copy of **VEN-A-CARE OF THE FLORIDA KEYS, INC.'S SUR-REPLY IN OPPOSITION TO ABBOTT LABORATORIES, INC.'S REQUEST FOR CERTIFICATION OF INTERLOCUTORY APPEAL UNDER 28 U.S.C. § 1292(b) AND STAY OF DISCOVERY PENDING APPEAL** was served via Lexis Nexis File and Serve upon all counsel of record according to CMO #2 on this 16th day of June 2008.

S//:Susan Schneider Thomas